



7/14
Docket No. 00263-4047

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SUMIDA, Shuji et al.

Serial No.: 09/622,487

Group Art Unit: 1654

Filed: August 17, 2000

Examiner: Jeffrey E. RUSSEL

For: PROTEIN-FREE FORMULATIONS

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APPLICANTS' STATEMENT OF SUBSTANCE OF INTERVIEW

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On July 2, 2003, Eugene Moroz and Karen Axt held a telephone interview with Examiner Russel to discuss this application. The courtesies extended by the Examiner are appreciated. A summary of the telephonic discussions between Examiner Russel and the representatives for the Applicants is set forth below.

Agreement as to amendments that would put the claims in condition of allowance was not reached.

Eugene Moroz suggested claim limitations as to storage time and temperature, which the Examiner rejected because the prior art Tsuji et al. and Japanese application no. 4-77436 provide no evidence that the compositions disclosed therein are unstable. The Examiner noted that stability was relative and nebulous and that comparative testing would be required to show stability of the claimed compositions over prior compositions. The Examiner suggested pH limitations of 5-6.5.

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Comparative testing was discussed further, and Eugene Moroz agreed to let the Examiner know whether Applicants would be willing to perform comparative tests to show greater stability to rebut the obviousness rejection. The Examiner indicated that the comparative tests should reproduce the compositions of the prior art and compare those compositions to those claimed under the conditions of the application specification, for example, the composition of claim 1 and practical example 2 of Tsuji et al. '117 patent at pH's within the range of Claim 1, at the times and temperatures disclosed in the specification.

On July 3, 2003, the Examiner was informed that Applicants will consider conducting comparative tests. The Examiner agreed to enter a timely filed §132 Declaration presenting the results of the comparative tests, provided that he is able to review the proposed test design in advance and approves it to the extent that it properly addresses the obviousness issues.

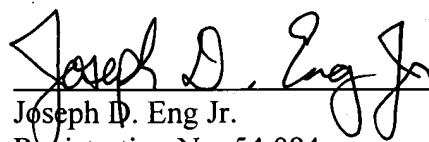
A Notice of Appeal was filed on July 3, 2003, with three months extension of time Petition and fee, pending the planning and execution of the comparative tests.

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-4500, Order No. 00263-4047.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: August 4, 2003

By:


Joseph D. Eng Jr.
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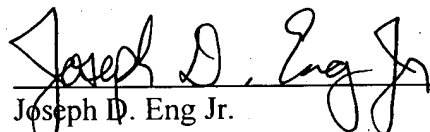
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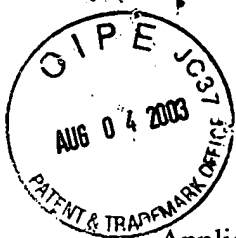
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Date of Deposit: **August 4, 2003**

I hereby certify that the following attached paper(s) and/or fee

1. Applicant's Statement of Substance of Interview;
2. Return Receipt Postcard.

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Shen

(Typed or printed name of person mailing papers(s) and/or fee)

(Signature of person mailing paper(s) and/or fee)

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